

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No. 40399/177/NIHD

In re patent application of

Jerry M. Keith

Serial No. 07/542,149

Group Art Unit: 1814

Filed: June 22, 1990

Examiner: G. Bugaisky

For: PERTUSSIS TOXIN GENE:  
CLONING AND EXPRESSION

DECLARATION OF JERRY M. KEITH

The Honorable Commissioner of  
Patents and Trademarks  
Washington, D.C. 20231

Sir:

I, Jerry M. Keith, hereby declare that:

(1) I am the named inventor in the above-identified application ("the subject application"). Prior to filing the subject application, I reviewed and understood the contents of the application, including the claims, which were directed to a "gene encoding...an antigenic mutant pertussis toxin with substantially reduced enzymatic activity."

(2) When the subject application was filed, I was named sole inventor through an error without deceptive intent. How the error occurred is detailed below:

(A) Prior to the subject application, I was deeply involved in cloning the pertussis toxin gene, an invention that is the subject of U.S. patent No. 4,883,761, filed in March 25, 1986. Research pertaining to the pertussis toxin gene continued under my supervision at Rocky Mountain Laboratories, NIAID (Hamilton, Montana) and involved a number of people. Among them was Dr. Witold Cieplak, whom I sponsored at the time under an NRC fellowship grant.

- (B) In the course of the preparation of the subject application, I sent a handwritten note to the patent agent responsible for the matter, Dr. Mishrail Jain, querying him concerning which individuals involved in the *pertussis* toxin gene project should be named as inventors. I clearly recall that he contacted me later by telephone to respond to my question. More specifically, I recall his telling me that he deemed the invention of the subject application, then in draft, to be an "continuation" of my earlier work on cloning the *pertussis* toxin gene, and that in his view this qualified me to be the sole inventor named in the application. Since I was not knowledgeable of the legal definition of "inventor," I accepted the oral assessment of Dr. Jain, who made no further inquiry, either of me or of my records, regarding inventorship in this case.
- (C) Sometime after the beginning of 1992, responsibility for the subject application passed to the law firm of Foley & Lardner. With this appointment of new counsel I had the opportunity to discuss at length various issues relating to the application with attorneys Stephen A. Bent and Colin G. Sandercock of Foley & Lardner. These discussions addressed, *inter alia*, the facts surrounding inventorship of the subject application, and led to the perception that Dr. Jain's previous, oral assessment of inventorship was suspect.

(3) This perception was followed up in a complete reevaluation of inventorship. The reevaluation occurred over several months, beginning in late March 1992, and involved the review of many contemporaneous documents as well as interviews of numerous individuals, including Dr.

Cieplak. The reevaluation prompted the realization, on or about October 5, 1992, that Dr. Cieplak likely was an inventor of the claimed invention. Further consideration prompted the conclusion, reached in late October, that Dr. Cieplak in fact was the sole inventor of the claimed invention.

(4) I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent resulting therefrom.

Nov 24, 1992  
Date

Jerry M. Keith  
Jerry M. Keith

**HAND CARRY TO U.S. PATENT & TRADEMARK OFFICE**

Case No.: 2026-4253US2

Serial No.: 07/311,612 Date Due N/A

Atty: BWB/crp

Date This Paper is being filed February 20, 2003

Applicants: Jerry M. KEITH.

Entitled: PERTUSSIN TOXIN GENE: CLONING AND EXPRESSION OF PROTECTIVE ANTIGEN

The return of this post card, properly stamped, will acknowledge receipt in the Patent & Trademark Office of the following:

1. Petition under 37 CFR 1.182 - 2 pgs. with supporting copies of the following documents - Date Stamped postcard evidencing documents filed on December 2, 1992 - 1 pg.; Petition for Correction of Inventorship - 3 pgs; Declaration of Jerry M. Keith - 3 pgs.; Declaration and Power of Attorney - 1 pg.; copy of Check # 249189 over 2003 of Petition for \$130.00; Date Stamped postcard evidencing filed Supplemental Submission with Consent of Assignee filed December 16, 1992 - 1 pg.; copy of Supplemental Submission with Consent of Assignee - 1 pg.; Declaration of Witold Cieplak, Jr. - 29 pgs.; Declaration of Witold Cieplak - 2 pgs.; Declaration of Jerry M. Keith - 1 pg.; USPTO Document - 1 pg..
2. Check No. 29383 the amount of \$130.00 for Petition Fee.- 12 pgs. (in duplicate).

41063 v1

**RECEIVED**

**MAR 2 8 2003**

**TECH CENTER 1600/2900**

**HAND CARRY TO U.S. PATENT & TRADEMARK OFFICE**

Case No.: 2026-4253US2

Serial No.: 07/311,612 Date Due N/A

Atty: BWB/crp

Date This Paper is being filed February 20, 2003

Applicants: Jerry M. KEITH.

Entitled: PERTUSSIN TOXIN GENE: CLONING AND EXPRESSION OF PROTECTIVE ANTIGEN

The return of this post card, properly stamped, will acknowledge receipt in the Patent & Trademark Office of the following:

1. Petition under 37 CFR 1.182 - 2 pgs. with supporting copies of the following documents - Date Stamped postcard evidencing documents filed on December 2, 1992 - 1 pg.; Petition for Correction of Inventorship - 3 pgs; Declaration of Jerry M. Keith - 3 pgs.; Declaration and Power of Attorney - 1 pg.; copy of Check # 249189 over 2003 of Petition for \$130.00; Date Stamped postcard evidencing filed Supplemental Submission with Consent of Assignee filed December 16, 1992 - 1 pg.; copy of Supplemental Submission with Consent of Assignee - 1 pg.; Declaration of Witold Cieplak, Jr. - 29 pgs.; Declaration of Witold Cieplak - 2 pgs.; Declaration of Jerry M. Keith - 1 pg.; USPTO Document - 1 pg..
2. Check No. 29383 the amount of \$130.00 for Petition Fee.- 12 pgs. (in duplicate).

41063 v1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE.

In re Application of Keith )  
Serial Number: 07/542,149 ) Art Unit: 1814  
Filed: June 22, 1990 ) Examiner: C. Low

For: PERTUSSIS TOXIN GENE: CLONING AND EXPRESSION

DECLARATION UNDER 37 CFR 1.131

Commissioner of Patents  
and Trademarks  
Washington, D.C. 20231

Sir:

I, Jerry M. Keith am named as the inventor in the above indicated patent application, and I state as follows:

1. That prior to July 1, 1988, a cloned gene coding for the expression of a mutant *Bordetella pertussis* toxin polypeptide fragment having substantially reduced enzymatic activity associated with pertussis toxin reactogenicity and retaining an epitope reactive with monoclonal antibody 1B7 was conceived and reduced to practice. This cloned gene and its expression product have the laboratory designation mutant 4-1. Mutant 4-1 possesses and exhibits the characteristics disclosed in Patent applications 07/311,612 and its continuation 07/542,149.

2. Exhibit pages 1-6 include laboratory notebook pages which demonstrate the reactivity of mutant 4-1 to monoclonal antibody 1B7. The data from these pages resulted in Figure 6B in Patent applications 07/311,612 and its continuation 07/542,149, and Figure 1B in Burnette et al. Science 242:72-74 (October 1988).

3. Exhibit pages 7-15 include laboratory notebook pages which demonstrate ADP-ribosyltransferase assays involving various pertussis toxin mutants, including a demonstration of substantially reduced enzyme activity associated with mutant 4-1. The data from these pages resulted in Figure 2A described in Burnette et al. Science 242:72-74 (October 1988), and the corresponding panel in Figure 6 of Patent applications 07/311,612 and its continuation 07/542,149.

4. Exhibit pages 16-25 include laboratory notebook pages which demonstrate NAD-glycohydrolase assays involving various pertussis toxin mutants, including a demonstration of substantially reduced enzyme activity associated with mutant 4-1. The data from these pages resulted in Figure 2B described in Burnette et al. Science 242:72-74 (October 1988), and the corresponding panel in Figure 6 of Patent applications 07/311,612 and its continuation 07/542,149.

5. The actual dates on laboratory notebook pages described in sections 2-4 above have been blocked out. I state that each laboratory notebook page in sections 2-4 above was dated prior to July 1, 1988.

6. The work corresponding to sections 1-5 above was carried out in the United States, and under my direction.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and

belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date Dec 19, 1991

Jerry M. Keith

Jerry M. Keith

EXHIBIT PAGE #1

Western blots - Angen mutants;

for stained gel - using solubilized inclusion bodies

Lane		
1	Blank	
2	BSA marker 5+1;	
3	PTx (5ug)	
4	GA	
5	1-1	
6	2-1	
7	3-1	
8	4-1	
9	5-1	
10	6-1	
11	7-1	
12	8-1	
13	GA-2	
14	Blank	
15	Blank	

5ug of inclusion body used;  
= 10ul/well;

protein 187

Western

Pattern gel only  
used the gel for protein

Lane	
1	Blank
2	BSA markers (one)
3	Blank
4	PTx (1ug) + up this
5	GA
6	1-1
7	2-1
8	3-1
9	4-1
10	5-1
11	6-1
12	7-1
13	8-1
14	GA-2
15	Blank

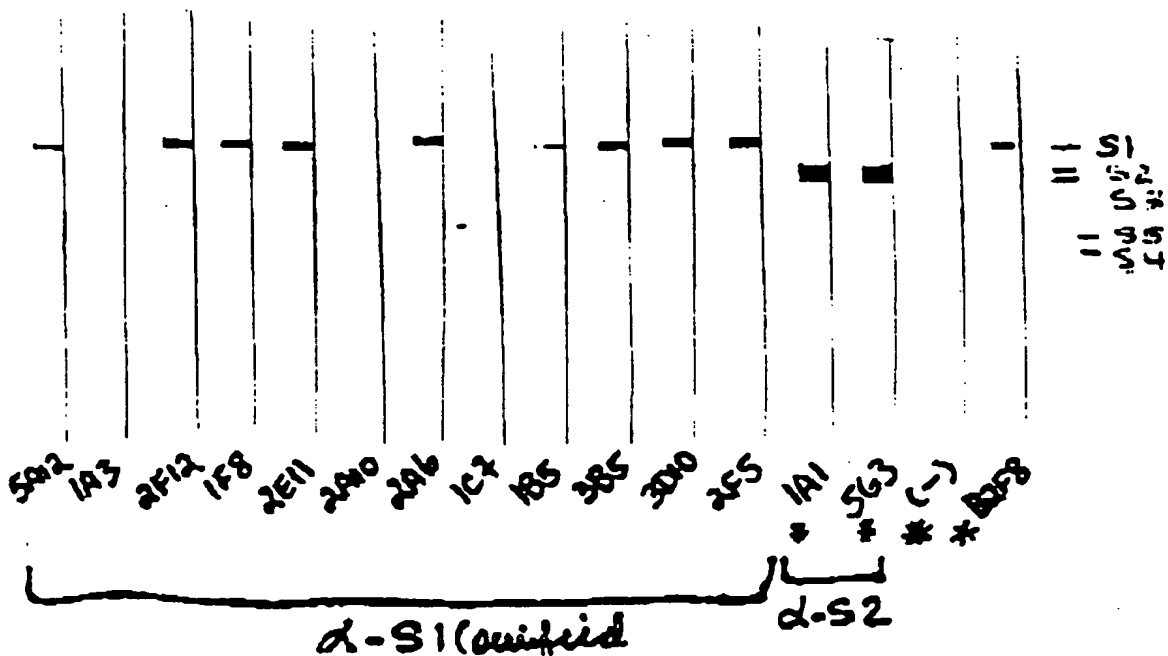
5ug (one) of inclusion body  
500ug of 15ug protein to 2ug protein;

6.0ug equivalents  
Marked by 2.0ug



EXHIBIT PAGE #2

PTX  
10ug



PTX 1A3 2F12 1F8 2E11 2A0 2A6 1C7 1B5 3B5 3D0 2F5 1A1 5G3 (-) B258

--✓-----=

Amgen mutant S1 proteins  
monoclonal 1B7

DocId: No. 00000710/0000

# DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

PERTUSSIS TOXIN GENE: CLONING AND EXPRESSION

the specification of which (check one)

☐ is attached hereto

☒ was filed on JUNE 22, 1990 as Application Serial No. 07/542,199 and was amended on October 5, 1992 (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is known by me to be material to patentability as defined in Title 37, Code of Federal Regulations § 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, § 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

## PRIOR FOREIGN APPLICATION(S)

NUMBER	COUNTRY	DAY/MONTH/YEAR FILED	PRIORITY CLAIMED

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s) listed below and insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose information which is known by me to be material to patentability as defined in Title 37, Code of Federal Regulations § 1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

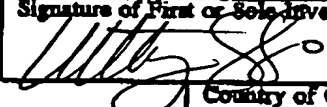
APPLICATION SERIAL NO.	FILING DATE	STATUS: PATENTED, PENDING, ABANDONED

I hereby appoint as my attorneys, with full powers of substitution and revocation, to prosecute this application and transact all business in the Patent and Trademark Office connected therewith: Reid G. Adler, 30,988; James C. Haight, 25,588; Marjorie D. Hunter, 30,560; Gloria Richmond, 30,416; Robert Beason, 33,612; Jack Spiegel, 34,477; Thomas G. Wiseman, 35,046; Dante J. Piscianno, 33,543; Susan S. Rucker, P-35,762; David R. Sadowski, 32,808; and Larry Hyman, 35,551.

I hereby appoint as my associate attorneys, with full power to prosecute this application and transact all business in the Patent and Trademark Office connected therewith: Arthur Schwartz, Reg.No. 22,115; Donald D. Jeffrey, Reg.No. 19,980; Richard L. Schwab, Reg.No. 25,479; Peter G. Mack, Reg.No. 26,001; David A. Blumenthal, Reg.No. 25,257; Joseph D. Evans, Reg.No. 26,269; John J. Feldhaus, Reg.No. 28,822; Stephen A. Best, Reg.No. 29,768; Bernhard D. Saxe, Reg.No. 28,665; Colin G. Sandercock, Reg. No. 31,298.

Send all correspondence to **FOLEY & LARDNER**, P.O. Box 299, Alexandria, VA 22313-0299.  
Address telephone communications to Stephen A. Best at (703) 836-9300.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full Name of First or Sole Inventor <b>Witold Cieplak, Jr.</b>	Signature of First or Sole Inventor 	Date <b>11/25/92</b>
Residence Address <b>Northwest 237 Hilltop Drive, Hamilton, Montana 59840</b>	Country of Citizenship <b>U.S. United States</b>	
Post Office Address <b>Northwest 237 Hilltop Drive, Hamilton, Montana 59840</b>		

Signatures should conform to names as typewritten. ☐ Additional inventors on attached Page 2.

Receipt is hereby acknowledged of the following:

Applicant : Jerry M. KEITH

Serial No.: 07/542,149 Docket No. 40399/177

Filing Date: June 22, 1990

For : PERTUSSIS TOXIN GENE: CLONING AND  
EXPRESSION

X Petition to Correct Inventorship (Fee 130.00)

X Verified Statement of Facts by J. Keith

X Declaration executed by W. Cieplak, Jr.

X Consent of Assignee

X File in Mail Room

Date 12/2/92

Return to SABE:kxd

Inspected By: \_\_\_\_\_

**FOLEY & LARDNER**

KING STREET STATION, SUITE 500

1800 DIAGONAL ROAD

ALEXANDRIA, VA 22314

68-107/560

No. 24919

MATCH THE AMOUNT IN WORDS WITH THE AMOUNT IN NUMBERS



24919  
? 1992

\*\*\*\*\* DEC 02 1992 ■ ONE HUNDRED THIRTY DOLLARS AND 00 CENTS

TO THE  
ER OF

**COMMISSIONER OF PATENTS & TRADEMARKS**

0304

40399177NIHD

07542149 KEITH

PET TO CRT INV

STATEMENT OF FACTS DECL ASSIGNEE

CRESTAR BANK  
ALEXANDRIA, VIRGINIA



MEMO: \_\_\_\_\_

⑈00024919⑈ ⑆1056001079⑆ 202165620⑈

Receipt is hereby acknowledged of the following:

Applicant : Jerry M. Keith

Serial No. : 07/542,149

Filing Date: June 22, 1990

EGSA-1042  
12/10/93

For

PERTUSSIS TOXIN GENE: CLONING AND EXPRESSION

☐ Amendment (Fee \_\_\_\_\_)

☐ Request for Extension of Time (1st) (2nd) (3rd)

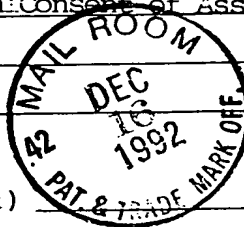
☒ Supplemental Submission with Consent of Assignee

☐

☐

☒ File in Mail Room

☐ File in Group (Art Unit)



Instructions \_\_\_\_\_

Date Due N/A

Return To KULENE/jaf

KYD

Inspected: bgh

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of

Jerry M. Keith

Serial No. 07/542,149

Group Art Unit: 1814

Filed: June 22, 1990

Examiner: G. Bugaisky

For: PERTUSSIS TOXIN GENE: CLONING  
AND EXPRESSION

SUPPLEMENTAL SUBMISSION

The Honorable Assistant Secretary and  
Commissioner of Patents and Trademarks  
Washington, D.C. 20231

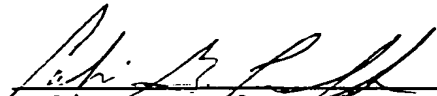
Sir:

Applicant encloses the original executed Consent  
of Assignee for the above referenced application to  
supplement the photocopy filed with the Petition to Correct  
Inventorship filed December 2, 1992.

Should there be any questions regarding this  
application, Examiner Bugaisky is invited to contact the  
undersigned attorney at (703) 836-9300.

Respectfully submitted,

12/16/92  
Date

  
Colin G. Sandercock  
Reg. No. 31,298

FOLEY & LARDNER  
P.O. Box 299  
Alexandria, Virginia 22313-0299  
Tel: (703) 836-9300  
Fax: (703) 683-4109

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: :  
                 Jerry M. Keith : Art Unit: 1814  
 Serial No.: 07/542,149 :  
 Filed: 06/22/90 : Examiner: G. Bugaisky

**Title:** PERTUSSIS TOXIN GENE: CLONING AND EXPRESSION

### Consent of Assignee

Hon. Commissioner of Patents and Trademarks  
Washington, D.C. 20231

**Dear Sir or Madam:**

The United States Department of Health and Human Services is assignee of the entire right, title, and interest in and to the above-identified application as shown by the assignment recorded on **February 15, 1989**, at Reel **5042**, Frame **0961**, in the patent assignment records of the U.S. Patent and Trademark Office. Said assignee hereby consents to the amendment of inventorship of this application to add the name of Witold Cieplak, Jr. as inventor, and to delete the name of Jerry M. Keith as inventor.

The National Institutes of Health Office of Technology Transfer has been duly delegated responsibility for such patent matters under the authority of the Department of Health and Human Services Secretary Louis W. Sullivan's May 21, 1991 memorandum appearing in the Friday, June 7, 1991 Federal Register Notices at Vol. 56, No. 110, pages 26418-26419, a copy of which is attached. The undersigned is authorized to exercise such authority in this matter.

Done on November 30, 1992, at Rockville, Maryland.

~~James C. Haight (25,588)~~

for: Reid G. Adler, Director  
Office of Technology Transfer  
National Institutes of Health  
Box OTT  
Bethesda, MD 20892  
Telephone 301/496-7056

DHHS #: E-171-86/2

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s): JERRY M. KEITH  
Serial No.: 07/311,612  
Filed: February 15, 1989  
For: PERTUSSIS TOXIN GENE: CLONING AND EXPRESSION OF PROTECTIVE ANTIGEN

Group Art Unit: 1653  
Examiner: Gabriele E. Bugaisky

**PETITION UNDER 37 C.F.R. §1.182**

Attn: Ms. Fran Hicks  
Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

Applicant respectfully petitions the Commissioner pursuant to 37 C.F.R. §1.182 to change and correctly identify the inventor in the instant application. Applicant respectfully petitions to have papers correcting the inventorship from Jerry M. Keith to Witold Cieplak as filed in application Serial No. 07/542,149 (“‘149 application”) be entered in the instant application. The ‘149 application is a continuation application claiming the benefit of the instant application under 35 U.S.C. §120.

The inventor of the subject matter of the instant application was identified in the original declaration, and subsequent application Serial No. 07/542,149, as Jerry M. Keith. However, upon evaluation of the inventorship performed during the pendency of the ‘149 application, the Agent of record discovered that Jerry M. Keith was not the true inventor. Rather, Witold Cieplak is the correct sole inventor. A request to correct inventorship and supporting declarations were submitted in the ‘149 application. Enclosed herewith is a copy of all papers to correct inventorship as filed in the ‘149 application.

Applicant respectfully asserts that the change of inventorship was not filed earlier due to

a misunderstanding with the Examiner in this application. In a Communication dated April 27, 1994 in the '149 application, the Examiner accepted applicants request to correct inventorship and specifically stated "The change in inventorship is permissible. It does not appear necessary to revive parent application 07/311,612 in order to grant priority (MPEP §201.3 re continuing applications)." However, now the Examiner insists upon correction of the instant application in order to perfect applicants' claim to priority under 35 U.S.C. §120.

The applicant hereby petitions the Commissioner to correct inventorship in application Serial No. 07/311,612. Applicant respectfully requests correction of the records in this application to identify this inventor as: WITOLD CIEPLAK.

A check for \$130.00 for filing this petition is enclosed herewith (37 CFR 1.17(h)).

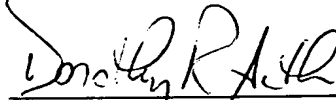
#### AUTHORIZATION

Should any additional fee(s) be required by the filing of this Amendment and accompanying papers, authorization is hereby given to the Commissioner to charge the amount of any such fee(s) that is/are properly assessable in this application to Deposit Account No. 13-4500, Docket No. 2026-4253US2. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,  
MORGAN & FINNEGAN, L.L.P.

Dated: February 19, 2003

By:

  
Dorothy R. Auth  
Registration No. 36,434

Correspondence Address:

MORGAN & FINNEGAN, L.L.P.  
345 Park Avenue  
New York, NY 10154-0053  
(212) 758-4800 Telephone  
(212) 751-6849 Facsimile



Case No. 2026-4253US2 Serial No. 07/311,612  
Date Mailed \_\_\_\_\_ ATTY DRA/EMK  
Date Due in the Patent Office \_\_\_\_\_

The return of this post card, properly stamped, will  
acknowledge receipt in the Patent & Trademark Office  
of the following:

- 1.- Petition Under 37 C.F.R. §1.182;
- 2.- Copy of all papers to correct inventorship as filed in  
the 07/542,149 application;
- 3.- Check in the amount of \$130.00 to cover petition  
fee; and
- 4.- Certificate of Hand Delivery.

RECEIVED

MAR 28 2003

TECH CENTER 1600/2900

**MORGAN & FINNEGAN, L.L.P.**  
**ATTORNEYS AT LAW**  
345 PARK AVE.  
NEW YORK, NY 10154

029383

1-8/210  
280

DATE 2/19/03

Security features  
are indicated  
on the back

**COMMISSIONER OF PATENTS AND TRADEMARKS**

\$ 130.00

**\$130.00**

DOLLARS

**CITIBANK**  
CITIBANK, N.A.  
153 EAST 53RD STREET  
FLOOR NO. 2411  
NEW YORK, N.Y. 10043

THE CITIBANK PRIVATE BANK

FOR 2026-4253US2 (KWON/Auth)

*[Signature]*

⑈029383⑈ ⑆021000089⑆ 400 37254776⑈

Receipt is hereby acknowledged of the following:

Applicant : Jerry M. KEITH

Serial No.: 07/542,149      Docket No. 40399/177

Filing Date: June 22, 1990

For : PERTUSSIS TOXIN GENE: CLONING AND  
EXPRESSION

- X Petition to Correct Inventorship (Fee 130.00)
- X Verified Statement of Facts by J. Keith
- X Declaration executed by W. Cieplak, Jr.
- X Consent of Assignee

X File in Mail Room

Date 12/2/92

Return to SABE:kxd

INSPECTED By: AH

*hvt* KXD

RECEIVED  
MAR 28 2003  
TECH CENTER 1600/2900

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No. 40399/177/NIHD

In re patent application of

Jerry M. Keith

Serial No. 07/542,149

Group Art Unit: 1814

Filed: June 22, 1990

Examiner: G. Bugaisky

For: PERTUSSIS TOXIN GENE: CLONING  
AND EXPRESSION

PETITION FOR CORRECTION OF INVENTORSHIP  
UNDER 37 CFR §1.48(a)

The Honorable Commissioner of  
Patents and Trademarks  
Washington, D.C. 20231

Sir:

Pursuant to 37 CFR §1.48(a), applicants hereby petition to amend the inventorship of the above-identified application ("the present application") to delete Jerry M. Keith as the sole inventor and insert Witold Cieplak as the sole inventor.

Filed concurrently with this petition are:

- (1) a verified statement of facts by Jerry M. Keith, which attests (i) that the incorrect inventorship arose through error without deceptive intention, and which also identifies (ii) when the error was discovered and (iii) how it occurred;
- (2) an declaration under 37 CFR §1.63 which executed by Witold Cieplak;
- (3) the written consent of the assignee, the U.S. Department of Health and Human Services; and
- (4) payment for the petition fee prescribed by applicable PTO rules.

Applicants believe that the appended payment to be sufficient. The Commissioner is authorized, however, to

**The Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 19-0741.**

RECEIVED

MAR 28 2003

TECH CENTER 1600/2900

charg any additional amount needed for this petition to PTO account No. 19-0741.

STATEMENT OF FACTS IN SUPPORT OF THIS PETITION

An error in the inventorship of this application was discovered during a recent investigation by Foley & Lardner, conducted on behalf of NIH in anticipation of a possible interference. See paper No. 7, entitled AMENDMENT UNDER 37 CFR §1.111 AND REQUEST FOR INTERFERENCE UNDER 37 CFR §§1.604 AND 1.607, which applicants filed on October 5, 1992.

The investigation revealed that Dr. Cieplak, who had worked closely with the presently-named inventor, Dr. Keith, in research pertaining to *Bordetella pertussis* toxin, in fact was responsible for conception of the subject matter claimed in the present application. In this regard, Dr. Keith attests that he had worked previously on the cloning of the *pertussis* toxin gene, which is the subject of U.S. patent No. 4,883,761. The *pertussis* toxin project, which continued under Dr. Keith's supervision, came to involve a number of individuals, including Dr. Cieplak, and led eventually to the preparation of an application directed to DNA coding for a mutant *pertussis* toxin ("the claimed invention").

Dr. Keith further attests that he consulted with responsible counsel regarding the proper constituency of an inventive entity for the new application. In particular, Dr. Keith was advised that he qualified as the sole inventor of the aforementioned DNA. No formal inquiry of Dr. Keith's records were made in this context, however, until present counsel undertook the investigation mentioned above. In late October, this investigation prompted the conclusion that Dr. Cieplak and not Dr. Keith was the sole inventor of the claimed invention.

Serial No. 07/542,149

In view of the foregoing, it is requested that the inventorship of this application be amended to name Dr. Cieplak as the sole inventor.

Respectfully submitted,

December 2, 1992  
Date

S. A. Bent  
Stephen A. Bent  
Registration No. 29,768

FOLEY & LARDNER  
P. O. Box 299  
Alexandria, Virginia 22313  
Tel: (703) 836-9300